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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,193	03/25/2002	Jean-Pierre Molitor	H 4157 PCT/US	1128
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23657 7590 05/05/2004

COGNIS CORPORATION
PATENT DEPARTMENT
300 BROOKSIDE AVENUE
AMBLER, PA 19002

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,193	MOLITOR ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-35 is/are pending in the application.
- 4a) Of the above claim(s) 22-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 1-4 is acknowledged.

The traversal is on the ground(s) that the examiner has not specifically described the unique special technical feature in each group and that the question should be whether the same technical feature is contained in each group and not whether the special technical feature actually makes a contribution over the art. However, applicant has not cited a suitable authority to substantiate the statements made.

In MPEP 1893.03(d) and 37 CFR 1.499 and relating to unity of invention during the national stage it is stated

“A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning **those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.** For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key.” (emphasis added).

As noted in the restriction requirement, the invention as claimed does not define a contribution over the art.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time

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any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15

are rejected under 35 U.S.C. 102(b) as being anticipated by Inlow *et al.* (U.S. Patent No. 5,372,943)

The claims are drawn to a reaction medium for fermentation processes comprising a microorganism and a product by process microemulsion of a certain droplet size.

The cited reference discloses a reaction medium comprising a microemulsion and the microorganisms insect cells, which is identical to the presently claimed composition (see, e.g., Example 8, Example 9 and Example 2) since the size distribution overlaps and it contains the same ingredients.

It is noted that the composition is claimed as containing a "phase inversion temperature emulsion", which constitutes claiming as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie obviousness or anticipation for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Consequently, the claimed composition is anticipated by the reference.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inlow *et al.* taken with Kopp-Holtwiesche (DE 3738812) and Forster *et al.* (WO 95/11660).

As indicated in the rejection under 35 U.S.C. § 102, *supra*, Inlow *et al.* discloses a reaction medium comprising a microemulsion and the microorganisms insect cells wherein the size distribution overlaps and which contains the same ingredients (see, e.g., Example 8, Example 9 and Example 2). The reference differs from the claimed invention a fatty acid methyl ester is not used in the medium. However, Kopp-Holtwiesche discloses a similar microbial reaction medium containing methyl laurate or other fatty acid methyl esters (See, e.g., Examples 1 and 3).

The references differ from the claimed invention in that at least Inlow *et al.* use an animal oil rather than a vegetable oil. However, Forster *et al.* adequately demonstrate that it is routine in

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Inlow *et al.* (U.S. Patent No. 5,372,943)

The claims are drawn to a reaction medium for fermentation processes comprising a microorganism and a product by process microemulsion of a certain droplet size.

The cited reference discloses a reaction medium comprising a microemulsion and the microorganisms insect cells, which is identical to the presently claimed composition (see, e.g., Example 8, Example 9 and Example 2) since the size distribution overlaps and it contains the same ingredients.

It is noted that the composition is claimed as containing a "phase inversion temperature emulsion", which constitutes claiming as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie obviousness or anticipation for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Consequently, the claimed composition is anticipated by the reference.

Claims 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inlow *et al.* taken with Kopp-Holtwiesche (DE 3738812) and Forster *et al.* (WO 95/11660).

As indicated in the rejection under 35 U.S.C. § 102, *supra*, Inlow *et al.* discloses a reaction medium comprising a microemulsion and the microorganisms insect cells wherein the size distribution overlaps and which contains the same ingredients (see, e.g., Example 8, Example 9 and Example 2). The reference differs from the claimed invention a fatty acid methyl ester is not used in the medium. However, Kopp-Holtwiesche discloses a similar microbial reaction medium containing methyl laurate or other fatty acid methyl esters (See, e.g., Examples 1 and 3).

The references differ from the claimed invention in that at least Inlow *et al.* use an animal oil rather than a vegetable oil. However, Forster *et al.* adequately demonstrate that it is routine

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in this art to use a variety of triglycerides for the production of various emulsions (See, e.g. page 5, last paragraph). The Forster *et al.* reference also discloses the use of two emulsifiers in combination wherein one acts as a coemulsifier (See, e.g., page 8) and various amounts and combinations of these emulsifiers. The emulsions are produced by the “phase inversion temperature” (PIT) method.

While the compositions of Forster are not explicitly disclosed as being reaction media containing microorganisms, it is well recognized in the art that cosmetic compositions such as those disclosed in the reference are not sterile upon opening and are highly susceptible to microbial degradation. Thus they clearly constitute “a reaction medium” and can reasonably be presumed to contain microorganisms as claimed.

The ranges of ingredient content discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of the amounts used in the reaction medium preparation for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

It is also noted that the composition is claimed as containing a “phase inversion temperature emulsion”, which constitutes claiming as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness or anticipation for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the reaction medium of Inlow *et al.* by substituting microemulsions containing animal oils with microemulsions containing fatty acid alkyl esters, and methyl esters in particular, as suggested by the teachings of Kopp-Holtwiesche and/or a variety of oils including specific vegetable oils as taught by Forster *et al.* (WO 95/11660), as well as altering the proportions of the various ingredients for optimization purposes for the expected economic benefit of enhancing the bioavailability of the lipids to recalcitrant microbial that will support their growth and proliferation as well as providing the option of not having the

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filter sterilize the lipid fraction and the rest of the media components separately. The growth and proliferation of recalcitrant microorganism has the expected benefit of increasing the yields of pharmaceutically and industrially important metabolites and/or aiding in the identification of pathogenic microorganisms.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651